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Infectious Disease Division
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David C. Hooper, M.D.
Associate Professor of Medicine
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Fellowship Program Director

March 19, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Re: Discussion paper: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals." Food and Drug Administration (FDA), Department of Health and Human Services (HHS)

Docket No. 98D-1146

I have reviewed the above referenced document and would like to provide the following comments.

As a co-chairman of the WHO Meeting on the Use of Quinolones in Food Animals and the Potential Impact on Human Health held in Geneva in June 1998 and as a physician and investigator in the field of quinolone resistance, I would commend the Center for Veterinary Medicine and FDA for their efforts to address the risks of antibiotic resistance in foodborne pathogens to human health and the relationship of this risk to use of antimicrobials in food-producing animals. The components of the framework for risk categorization are I believe based on sound general principles. The consequences of how these principles are implemented and applied, however, will require careful consideration, and understandably cannot be addressed in full detail in a "framework" document. The difficulties that these issues may pose should not, however, forestall or reduce efforts to move the process of development forward with due consideration. Because of the complexity of issues of assessing thresholds and establishing monitoring requirements, it would seem most effective to convene small working groups of representative experts with detailed knowledge of animal and human health to assess specific approaches within the framework and to make recommendations to FDA on how specifically to translate principles into practice.

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I would like to comment additionally on two specific portions of the framework document. First, I believe that monitoring of resistance is integral to the effectiveness of the program and that the results should be subject to regular review. I think, however, that there are currently insufficient data to be able to define a specific resistance threshold below which protection of human health could be assured. I would favor monitoring of both human and animal isolates for levels of resistance. Animal data may be more sensitive but human data more specific for assessing the relation of antibiotic use and resistance to human health.

Second, I would urge consideration of a national on-farm program for monitoring of resistance as well as for collecting information on antibiotic use. In general, correlations of resistance with drug sales data by geographic region may be masked by difficulty in accurately accounting for drug use. Thus, an on-farm program in which resistance and antibiotic use could be monitored at the point of that use may be advantageous. Additionally, mitigation efforts (e.g. change in litter disposal practices) could also be readily assessed at the level of the farm as part of an ongoing monitoring process.

I appreciate your consideration of these comments.

Sincerely,

David C. Hooper, M.D.

If not delivered in five days return to:

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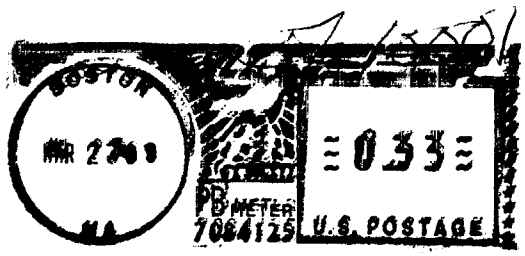

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a. The hematocrit of the final red blood cell product as determined by the method described in the device operator's manual.

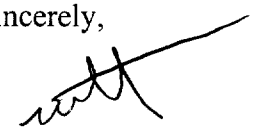
b. An absolute red blood cell volume of each product produced. (Red Blood Cell product hematocrit X Red Blood Cell product volume).

c. A comparison of the calculated donation volume and the pre-determined target volume as determined by the donor's gender and hematocrit.

Justification: The data developed and submitted to the FDA in support of the 510(k) demonstrated that the Haemonetics MCS+ produces a more consistent volume red cell product than a red cell product produced via whole blood collection. In addition, all manufacturers will have to validate the process prior to implementation in their facility. Finally, blood collection using the Haemonetics MCS+ is operated as a validated process monitored by periodic product quality control sampling so that performing product quality control examinations on every red cell product produced is unnecessary.

Red Cross appreciates the opportunity to provide comments on the guidance. If you have any questions, please contact Bill Kline, Director, Business Operations at 313-494-3422.

Sincerely,



Glenn M. Mattei, Esq.
Senior Director,
Quality Assurance & Regulatory Affairs
American Red Cross

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